ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
1475 ΛΕΥΚΩΣΙΑ

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 LEFKOSIA

Our ref.:PhS. 5.21.2.1, 4.2.17
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22 August 2011

Heads of Agencies for Human Medicinal Products

Dear Sir / Madam

Repeat Mutual Recognition Procedure (rMRP): Administrative (or Zero Days) Repeat MRP with Cyprus as the only CMS.

1. We wish to inform you that Cyprus, will introduce a new simplified procedure for accepting applications for the issue of a marketing authorisation for medicinal products for human use, already approved through the MR or DC procedures based on the experience of a similar procedure followed by other member states. This repeat MR procedure will be of administrative nature and will be concluded immediately after the submission of a valid application (Administrative rMRP or Zero days rMRP).

2. The procedure is in accordance with Directive 2001/83/EC and we believe that will help improve availability of medicinal products in the Cypriot market. The procedure will be extending the Marketing Authorisation (MA) of Medicinal Products (MP) for human use to Cyprus, without creating significant administrative or scientific burden to the RMS, since no update of the Assessment Report is required. Also, it will not create any concerns to the Applicant for a new or duplicate assessment or changes in the products' approved information or lifecycle timelines (e.g. PSUR, Renewal).

3. The procedure will be applied as follows
   a. The Applicant informs in writing Cyprus (The Registrar Drugs Council) that is interested to follow the rMRP Zero Days and submits the following information
      i. Name of the product, dosage form, strength, active ingredient
      ii. The MRP / DCP Procedure number
      iii. The currently approved SPC of the product.
   b. The Drugs Council examines the intention letter and authorises in writing the procedure to start or informs the applicant about any possible objections that may has.
   c. The applicant contacts the RMS and submits an application for an rMRP Zero Days, with Cyprus as the ONLY Concerned Member State.

d. The Applicant submits an rMR Procedure application to Cyprus with a cover letter and the Dossier available at that time, together with any subsequent approved variations and a confirmation of their approval. If the Applicant has an updated Dossier available he may, preferably, submit it as this will accelerate the approval procedure. The Applicant in his cover letter must clearly state that the submitted dossier is identical as the one already approved in the RMS. Applications in either paper or electronic format (eCTD or NeeS) are accepted, but we strongly suggest the submission of eCTD.

e. Cyprus confirms in the CTS or via eudramail that no day 50 comments will be submitted and the RMS closes the procedure. After that, the usual 30 days national phase follows.

4. For valid rMRP Zero Days applications (as above), Cyprus commits that:

- There will be no need for the RMS to update the existing Assessment Report. Assessment Reports from the RMS will be accepted without any comments.
- No 50 day comments will be submitted thus, practically the application will be approved immediately (Zero Days).
- The addition of Cyprus as a CMS will not create a different renewal or PSUR timeline.

5. Agencies acting as RMS to the above procedure may consider charging a lower fee, as the procedure will be of administrative nature only and will not involve an update of the Assessment Report, or any other scientific assessment, and will not affect the Marketing Authorisation already issued in the RMS.

6. For further information you may contact the Registrar Drugs Council (c/o Ms. E. Mavrokordatou: emavrokordatou@phs.moh.gov.cy).

George Antoniou
Registrar Drugs Council

(Signed copy available)